

Remarks

Amendments to the Specification

At the request of Examiner Stephens, the abstract has been amended to be less than 150 words. For the Examiner's convenience, a clean copy of the abstract, on a separate page, is submitted at the end of this amendment.

Amendments to the Claims

Prior to this amendment, claims 1-48 were pending in this application. Claims 2, 6, 8, 10-11, 18-19, 21, 24-25 and 44 have been amended.

Reconsideration of the rejection of the claims is requested.

Claims 6 and 20 are amended to correct an obvious typographical error.

The amendment to Claim 8 is supported at page 3, line 6. The amendments to the remaining claims are rewordings or clarifications of the claim that do not add new matter.

New claims 49-51 are supported by original claim 25 and page 14, line 21 of the specification. New claim 52 is supported at page 13, line 23.

Claim Objections

Claim 19 has been amended to overcome the objections asserted in the Office action.

Allowable Subject Matter

Claims 44-48 were indicated to be allowable if rewritten in independent form. They have been so rewritten.

Prior Art Rejections

Claims 1-6

Independent claim 1 and dependent claims 2-6 are not obvious over U.S. Patent No. 3,983,873 (Hirschman). Hirschman teaches an interlabial pad useful for collecting urine or vaginal discharge from a subject (see col. 2, line 46-51). Hirschman is completely silent about anal leakage and certainly does not disclose or imply any method of absorbing such leakage. The Office even admits Hirschman does not disclose a method for absorbing leakage from an

anus of a subject (see Office Action, page 3, lines 12-13). The Office contends that the pad disclosed in Hirschman is identical to the pad provided in the method recited in claims 1-6, and asserts (without citing any evidence) that “it is within the level of one of ordinary skill in the art to use the pad for anal leakage.” This rejection unsupported by evidence does not establish a *prima facie* case of obviousness, and the claims are therefore allowable. A *prima facie* case requires that all elements of the claimed invention be shown or suggested by the cited references. See MPEP 2143.03. However, none of the cited references disclose or suggest positioning an intergluteal absorbent pad external to the subject’s anal orifice such that the pad is retained between the buttocks, as in claim 1. In addition, none of the cited references disclose absorbing discharge from the anus in the absorbent material of the pad, as in amended claim 2.

In accordance with M.P.E.P. 904, it is presumed that a full search was conducted and this search is indicative of the prior art. This search failed to disclose a reference which would teach or suggest modifying the Hirschman reference to achieve the method of claims 1-6. Consequently, the search revealed that the asserted modification is not known in the art and therefore, is not entitled to be relied upon in order to reject claim 1 and dependent claims 2-6.

Applicants would like to point out the requirement to reasonably challenge statements by the Office that are not supported on the record, as failure to do so will be construed as an admission by Applicants that the statement is true (M.P.E.P. §2144.03). Therefore, in accordance with Applicants’ duty to reasonably challenge such unsupported statements, the Office is hereby requested to cite a reference supporting the position that it would have been obvious to utilize the interlabial pad disclosed in Hirschman in accordance with the method of claims 1-6. If the Office is unable to provide a reference that discloses or suggests the modification, and is relying on facts based on personal knowledge, Applicants hereby request that such facts be set forth in an affidavit from the Examiner under 37 C.F.R. 1.104(d)(2), such that, the Applicants may rebut the unsubstantiated assertions. Further, it is to be noted that “Official Notice” is to be limited to instances where the facts are “capable of instant and unquestionable demonstration as being well-known.” M.P.E.P. 2144.03. Absent such substantiation by the Examiner, it is respectfully requested that the rejection under 35 U.S.C. § 103 be withdrawn.

The sole reason set forth in support of the rejection is that the claimed structure of the pad is known (from Hirschman), and that the claimed method only recites a method for using the

structure “which is similar to Hirschman.” The Office action therefore concludes it “is within the level of one of ordinary skill in the art to use the pad for anal leakage.” However such an assertion by itself is an inadequate basis for a *prima facie* case of obviousness, as noted in MPEP 2143.01.IV. A mere assertion of obviousness does not establish a *prima facie* case of obviousness in the absence of evidence that the prior art disclosed or suggested using an intergluteal pad to absorb anal leakage, as claimed. The specific method of claim 1 (positioning the intergluteal absorbent pad to absorb leakage) or claim 2 (absorbing the leakage) is not even hinted at by the references, which are completely silent about such a method. None of them even mention intergluteal placement of the pad, so they can hardly be said to disclose or suggest the claimed method.

Moreover, it would frustrate the purpose and function of the primary reference (Hirschman) to place the pad between the buttocks external to the anal orifice, as claimed. That reference explicitly states that it “an object of the invention is to provide improved feminine hygiene pads *for placement in the interlabial space....*” (column 1, lines 20-22, emphasis supplied). It would contravene the stated object and frustrate the purpose of the primary reference to place the pad (as claimed) between the buttocks, external to the anus, contrary to the stated object of Hirschman to place the pad in the *interlabial* space. An intergluteal pad would not serve the stated object of the Hirschman patent “for use by females” to absorb discharges such as “urine, vaginal secretions, post-coital leakage, menstrual staining, or the like” (Hirschman, column 1, lines 5-8).

The Office action stated that a claim is anticipated if a claim recites using an old composition or structure if the “use” is directed to a result or property of the composition of structure. However the rejection being asserted is an obviousness rejection and not an anticipation rejection; the cases cited in the Office action are therefore inapposite.

For the above reasons, the Office has not presented a *prima facie* case of obviousness with respect to independent claim 1, and dependent claims 2-6. Therefore, these claims are allowable, and Applicants request that the rejection be withdrawn.

Claim 7

Claim 7 is not obvious as alleged over Hirschman in view of U.S. Patent No. 5,074,855 (Rosenbluth *et al.*). For the reasons stated above, Hirschman does not teach a method for

absorbing leakage from an anus of a subject. The Office contends that it would have been obvious to modify the pad disclosed by Hirschman to include agent for absorbing odors as allegedly disclosed by Rosenbluth *et al.* However, Rosenbluth *et al.* does not disclose including an agent for absorbing odors. In fact, both Rosenbluth *et al.* and Hirschman are completely silent about odor absorbing agents. The passage cited by the Office in the rejection of claim 7 (Rosenbluth *et al.* col. 5 line 7-11) makes absolutely no mention of odor absorbing agents. A *prima facie* case of obviousness requires that the cited references disclose each and every element of the claim. The cited references do not disclose including an agent for absorbing odors, and the Office action therefore fails to establish a *prima facie* case of obviousness.

Furthermore, the Office has failed to establish a *prima facie* case of obviousness because it has not established that there is a suggestion or motivation to modify the references (see M.P.E.P. 2143.01). The references themselves teach away from the proposed combination of Hirschman and Rosenbluth *et al.*, as Rosenbluth *et al.* states explicitly that use of the absorbent pad of Hirschman is to be avoided (Rosenbluth *et al.* at col. 1, lines 60-61 specifically identifies Hirschman U.S. Pat. No. 3,983,873 as the disadvantageous prior art in which absorbent pads absorb liquid discharges). “A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” M.P.E.P. 2131.02, citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). One of ordinary skill in the art would not modify the absorbent pad of Hirschman using a reference that teaches that the absorbent pad of Hirschman is to be avoided.

For these reasons, the cited references fail to establish a *prima facie* case of obviousness with respect to claim 7 and it is allowable. In addition, claim 7 depends from claim 1 and is allowable for that reason as well.

Claim 8

Claim 8 has been amended to state that the pad carries a therapeutically effective amount of a medicinal agent that is dispensed from the pad for anal delivery, and the subject is in need of treatment of the medicinal agent. Claim 8 is not obvious over Hirschman in view of Rosenbluth *et al.* As stated above, Hirschman does not teach a method for absorbing leakage from an anus of a subject by placing the intergluteal absorbent pad between the buttocks. The Office also

admits at page 4, that Hirschman does not disclose a therapeutically or diagnostically effective amount of a diagnostic or therapeutic agent. The Office contends that it would have been obvious to modify the pad disclosed by Hirschman to include a diagnostically effective amount of a diagnostic or therapeutic agent allegedly disclosed by Rosenbluth *et al.* However, Rosenbluth *et al.* does not disclose the claimed method in which the intergluteal pad carries a therapeutically effective amount of a medicinal agent that is dispensed from the pad for anal delivery. None of the cited references even mention the use of an intergluteal absorbent pad, much less the anal delivery of a medicinal agent to treat a subject in need of the agent. In the absence of any such disclosures there is not even a colorable *prima facie* case of obviousness, and the rejection must be withdrawn. Any obviousness rejection would have to rely on hindsight reconstruction of the claimed invention using the inventors' own disclosure, which would be inappropriate.

Claim 9

Claim 9 further states that the medicinal agent is an anesthetic or lubricant. The cited references do not disclose or suggest such a specific agent; at most Rosenbluth *et al.* mentions an antibacterial or germicidal agent, such as silver oxide or silver azide. Neither of these agents is an anesthetic or lubricant, and in the absence of a specific disclosure of the claimed limitations a *prima facie* case of obviousness has not been established. Claim 9 is therefore allowable.

Claim 10

Claim 10 recites a method of placing the pad between the buttocks of the subject and absorbing excess anal leakage in the form of fecal material, glandular secretions, and/or blood. The cited references are silent as to anal leakage, fecal material, glandular secretions, and/or blood. "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). (M.P.E.P. 2143.03). Since the references do not even mention placing an absorbent pad between the buttocks to absorb fecal material, glandular secretions, and/or blood, they are not able to disclose or suggest the claimed method. The cited references do not support an obviousness rejection, and claim 10 is allowable.

Claim 11

Claim 11 recites placing the pad between the buttocks of the subject and absorbing suppository leakage, flatulence, hemorrhoid bleeding, fissure bleeding, or fecal incontinence. The cited references are silent about any of these conditions, or absorbing any of these materials, and therefore can not be said to disclose or suggest the claimed method. There is no evidence in the cited references that one skilled in the art would use the cited catamenial products for any of these purposes. Claim 11 is therefore allowable.

Claims 12 and 13

Claim 12 recites positioning an intergluteal absorbent pad external to the subject's anal sphincter, against the anal orifice. Claim 13 recites a method wherein the pad has a tapered leading edge that is inserted between the subject's buttocks to push the buttocks apart as the leading edge of the pad is inserted between the buttocks. Hirschman is silent as to an anal pad or a method of positioning a pad against the subject's anal orifice or between the subject's buttocks. Therefore, Hirschman does not teach all of the limitations of claim 12 or 13, and does not establish a *prima facie* case of obviousness with respect to those claims.

Claims 14 and 15

Claims 14 and 15 are allowable for the reasons set forth in connection with claims 1 and 13, from which they depend.

In addition, claim 15 states that the pad is positioned adjacent and external to the anal orifice but not the vaginal orifice. Such a modification of the catamenial devices shown in the cited references would defeat, frustrate and destroy the intended purpose of the cited references. The prior art catamenial devices would cease to function for their intended purpose (collecting menstrual fluid) if they were positioned at the anal orifice and not the vaginal orifice. A *prima facie* case of obviousness has not been established when such a modification of the cited references must be made.

Claims 16 and 17

Claims 16 and 17 are rejected over Hirschman in view of U.S. Patent No. 4,920,045 (Okuda *et al.*). The Office contends that it would have been obvious to modify the pad disclosed

by Hirschman to include the diagnostic test as allegedly disclosed in Okuda *et al.* Neither Hirschman nor Okuda *et al.* suggest performing a diagnostic test on a pad used for the collection of anal discharge. Absent such a suggestion, the cited references (even if combined) do not disclose all the elements of the claim. The Office has failed to provide a *prima facie* case of obviousness for claims 16 and 17.

The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. It is impermissible to use the claimed invention as an instruction manual or “template” to piece together the teachings of the prior art so that the claimed invention is rendered obvious. “One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.” In re Oetiker, 977 F.2d 1443, 24 USPQ 2d 1443 (Fed. Cir. 1992) quoting In re Fine, 837 F.2d 1071, 1075, 5 USPQ 2d 1596, 1600 (Fed. Cir. 1988). See also M.P.E.P. § 2141 and Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 220 USPQ 182, 187 n.5 (Fed. Cir. 1986). The Office has not met this burden and thus has not presented a *prima facie* case of obviousness for claims 16 and 17.

The mere fact that Okuda *et al.* discloses that diagnostic tests can be performed on fecal material does *not* suggest that the claimed method of positioning an intergluteal pad external to the subject’s anal orifice could be used to collect fecal material for performing a diagnostic test. Okuda only discloses using a collecting spoon or spatula to collect feces (column 4, lines 67-68). This in no way discloses that fecal material could be collected on the absorbent pad positioned external to the subject’s anal orifice. Even if all the references were combined they would not produce the claimed invention, which conclusively shows that a *prima facie* case of obviousness has not been established with respect to claims 16 and 17.

Claims 18 and 20

Independent claim 18 and dependent claim 20 are not obvious over Hirschman, as alleged in the Office action. Claim 18 is directed to a method of absorbing leakage from a subject’s anus by inserting a pad into the subject’s intergluteal space, positioning the pad adjacent to the subject’s external orifice, and absorbing the leakage from the subject’s anus into the pad. As already noted, the references are silent about placing a pad in this position, and absorbing leakage from the anus into the pad. In the absence of any mention of these multiple elements of

the claim, it is not possible to establish a *prima facie* case of obviousness. A mere assertion of obviousness in the absence of the disclosure of multiple elements of the claim is insufficient to support a *prima facie* case. Claim 18 (and its dependent claim 20) are therefore allowable.

Claim 19

Amended claim 19 states that the pad includes an odor-absorbing agent. The cited references are silent about including an odor absorbing agent in the pad, and they therefore are incapable of establishing a *prima facie* case of obviousness. The cited references do not address the problem of reducing anal odors; since they do not even concern the problem being solved they can hardly be said to suggest the claimed solution.

As noted above, the references themselves teach away from the proposed combination of Hirschman and Rosenbluth *et al.* Rosenbluth *et al.* states explicitly that use of the absorbent pad of Hirschman is to be avoided, thus one of ordinary skill in the art would not modify the absorbent pad of Hirschman using a reference that teaches that the absorbent pad of Hirschman is to be avoided. The Office has not met the burden of establishing a *prima facie* case of obviousness because it has not established that there is a suggestion or motivation to modify the references.

Claim 21

Claim 21 states the pad is elongated, and when placed in the intergluteal space extends external to the anal orifice and a vaginal opening. The prior art is completely silent about placing any intergluteal pad over both the anal and vaginal openings. The Office action does not explain how a *prima facie* case of obviousness can be established under such circumstances. Claim 21 is therefore allowable.

Claim 22

Claim 22 is not obvious over Hirschman in view of Rosenbluth *et al.* For the reasons stated above, Hirschman does not teach a method for absorbing leakage from an anus of a subject. As noted above, Hirschman and Rosenbluth *et al.* have been improperly combined. The Office admits at page 4, that Hirschman does not disclose a therapeutically or diagnostically effective amount of a diagnostic or therapeutic agent. The Office contends that it would have

been obvious to modify the pad disclosed by Hirschman to include a diagnostically effective amount of a diagnostic or therapeutic agent allegedly disclosed by Rosenbluth *et al.* As stated previously, Rosenbluth *et al.* does not disclose including therapeutically or diagnostically effective amount of a diagnostic or therapeutic agent. Thus all of the elements of claim 22 are not taught by the cited references.

Even more significantly, claim 22 is directed to a method of delivering the medicinal agent to a subject by placing a pad externally against the anus of a subject. This is a new delivery mechanism for administering a drug. The cited references do not concern a system for anal delivery of drugs, nor can they be said in any way to address or suggest the claimed invention.

The cited references therefore fail to establish a *prima facie* case of obviousness with respect to claim 22, and it is allowable.

Claim 23

Claim 23 is allowable for the reasons set forth in connection with the discussion of claim 9.

Claims 24-28

Claim 24 recites a method of providing a pad that absorbs anal leakage in the form of fecal material, glandular secretions, and/or blood. Claim 25 recites a method of providing a pad that absorbs anal leakage in the form of suppository leakage, flatulence, hemorrhoid bleeding, anal fissure bleeding, or fecal incontinence. Claim 26 recites positioning an intergluteal absorbent pad external to the subject's anal sphincter. Claim 27 recites a method wherein the pad has a tapered leading edge that is inserted between the subject's buttocks to push the buttocks apart as the leading edge of the pad is inserted between the buttocks. "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) and M.P.E.P. 2143.03. Hirschman is silent as to all of these limitations and thus the Office action has not established a *prima facie* case of obviousness with respect to claims 24-28.

Claims 29 and 30

Claims 29 and 30 are allowable for the reasons set forth in connection with claim 17.

Claims 31-41

Independent claim 31 and dependent claims 32-41 are directed to a method of treating a symptom of a subject with hemorrhoids. The claim was rejected as obvious in view of Hirschman, which only teaches the use of an interlabial pad for collecting urine or vaginal discharge from a subject. Hirschman fails to disclose multiple elements of claim 31, such as treating a symptom of a subject with hemorrhoids and positioning a pad adjacent to the subject's anus. The Office contends that the pad disclosed in Hirschman is identical to the pad of claims 31-41, and asserts, in the absence of evidence, that one of ordinary skill in the art would utilize the interlabial pad disclosed in Hirschman to practice the method of claims 31-41. Such an allegation constitutes hindsight reconstruction of the claimed invention in view of the inventors' own disclosure, and can not support a *prima facie* case of obviousness.

For the above reasons, the Office has not presented a *prima facie* case of obviousness with respect to independent claim 31, and dependent claims 32-41. Therefore, these claims are allowable, and Applicants request that the rejections be withdrawn.

Claims 42 and 43

Claim 42 and 43 are allowable for the reasons set forth in connection with claim 9.

Claims 44-48

Claim 44-48 were indicated allowable.

Conclusion

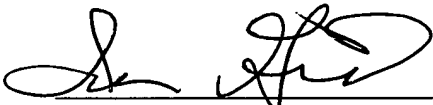
A *prima facie* case of obviousness has not been established by the Office action because the claimed subject matter is not disclosed or suggested by the cited references. Multiple elements of the claims are absent from the cited references, and the applicants' own disclosure can not be used in a hindsight reconstruction of the claimed invention. Applicants request that the outstanding rejections be withdrawn.

Applicants believe that the claims are in condition for allowance, and a notice to this effect is requested. If any matters remain before a Notice of Allowance is issued, the examiner is invited to telephone the undersigned at the telephone number below to discuss the case.

Respectfully submitted,

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